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CLAIMS

[Claim(s)]

- 1. Two or More Sensors Which are Equipment Which Carries Out Analysis of Qualitative Both or One of the Two to Somnipathy being Quantitive, and Detect Physical Action, The working recorder connected to the sensor in order to record the signal which the sensor measured, Equipment which carries out analysis of qualitative both or one of the two to the somnipathy which consists of a computer connected to the recorder in order to memorize and analyze the measured signal, and is characterized by forming at least one sensor chosen from the following groups being quantitive.
- (a) A means to detect the respiratory sound (4)
- (b) A means to detect positive pressure breathing (11)
- (c) A means to detect respiration rate (5)
- (d) A means to detect respiratory activities (6 7)
- (e) A means to detect heart potential (9)
- (f) A means to detect the oxygen content of blood (10)
- (g) A means to detect a body posture (12)
- (h) A means to detect body actuation (8)
- (i) Equipment concerning claim 1 with which a means 2. respiratory-sound detection means (4) to detect an electronic physiological parameter has an electric microphone.
- 3. Equipment concerning claim 1 or 2 with which means (9) to detect heart potential has three ECG electrodes.
- 4. Equipment concerning any one of the claims 1-3 which has pulse type oxygen analyzer to whom means (10) to measure oxygen content of blood has different sensor.
- 5. Equipment which requires means (12) to detect body posture for any one of the claims 1-4 which has four mercury switches for five measurement of the body.
- 6. Equipment which requires means (8) to detect actuation of the body for any one of the claims 1-5 which has piezo-electric element.
- 7. Equipment which requires means (11) to detect positive pressure breathing for any one of the claims 1-6 which has pressure sensor.
- 8. Equipment which requires means (5) to detect respiration rate for any one of the claims 1-7 which has heat element.
- 9. Equipment which requires means (5) to detect respiration rate for any one of the claims 1-7 which has thermistor.
- 10. Equipment which requires a means (6 7) to detect respiratory activities for any one of the claims 1-9 which has a piezo-electric element.
- 11. Equipment concerning any one of the claims 1-10 with which a means (6) to detect respiratory activities is united with a means (12) to detect a body posture.
- 12. Equipment concerning any one [equipped with a means (14) to record an external migration signal] of the claims 1-11.
- 13. Equipment concerning any one [equipped with at least one alarm generating machine] of the claims 1-12.
- 14. Equipment concerning any one of the claims 1-13 with which an alarm generating machine supervises the oxygen content of blood.
- 15. Equipment concerning any one of the claims 1-13 with which an alarm generating machine

supervises a heartbeat.

- 16. Equipment concerning any one of the claims 1-15 in which the means for also taking a noise signal into consideration was formed.
- 17. Equipment concerning any one of the claims 1-16 which could be made to perform a setup of the program of equipment according to desired use.
- 18. Equipment concerning any one of the claims 1-17 suitable for quiescence actuation and movable actuation.
- 19. Equipment concerning any one [equipped with the means which carries out correlation with a respiratory signal and a heart physiological signal, comparative / both /, and one side] of the claims 1-18.
- 20. Equipment concerning any one [equipped with a means to detect rate change of a pulse wave] of the ******* 1-19.
- 21. It is Approach for Quantitive Analysis of Somnipathy. The process which programs a recorder (3) according to a desired inspection, The process which records the data offered from at least one sensor controlled by the recorder (3), The process which supplies data to a computer (1) for analysis, Analysis of the data based on correlation of a -signal curve, and process which pulls out the further data from the recorded data Process which displays data in either or all the formats of signal curve, a table, and a histogram Approach characterized by containing.

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DETAILED DESCRIPTION

[Detailed Description of the Invention]

The quantitive analysis apparatus and approach of a somnipathy It is related with this invention detecting, recording and analyzing fluctuation of respiratory insufficiency, a heart beat failure, an involuntary convulsion, and blood pressure, a sleep parameter, an operational parameter, a failure, a defect parameter, etc. which start sleep in quiescence and the migration condition especially about quantitive analysis apparatus and approach of a somnipathy or dysnystaxis.

In view of the increment in the number of patients which lapses into dysnystaxis, and the increment in the burden of the sleep laboratory which makes dysnystaxis a speciality, the inspection and measurement of a failure with a working instrument have been shifted from a quiescence mold to a migration mold. Operating of the sensors connected to these equipments is explained to a patient, after measurement finishes, a working recording device is returned to a doctor in charge, and a medical practitioner analyzes this recorded signal and draws a diagnosis based on that result. This portable type approach is very cheap although measurement takes long duration, and further, for a patient, even if it carries out measurement implementation under a new environment, it does not affect a result.

Such a portable type recorder is EP-A -0. 356 It is indicated by 603. This recorder can perform record of the measurement signal by the means of eight channels, and that storage and subsequent analysis by computer. According to this, according to a clinical feature or the diagnostic purpose, the number of the data which should be measured by prior selection can be reduced, and a recorder can be programmed in many ways to extract only to desired measurement data. such -- it differed -- with programming, it changed variously -- it can be variously made adapted for an environmental condition

It is engaged in the measurement of a different parameter for somnipathy detection, and is DE-A -41. 38 Reference is made by 702. The equipment currently indicated there is equipped with the sensor which detects the oxygen density in the potential of the heart, the respiratory sound and a stertor sound, and blood, a patient's posture, etc. A diagnosis of an apnoea can be performed by analyzing the measured result. However, this analysis apparatus has the instrument which was limited to the detection for the purpose of [one] application (apnoea) (i.e., a somnipathy), therefore was limited to this specific purpose including the above-mentioned sensor, and was designed. Although especially the detection of respiratory insufficiency involved in sleep is possible, the side effect which accompanies this, for example, a heart beat failure etc., is undetectable.

It is related with this advanced technology and is DE further. 92 04 190 U1 DE32 48 222 A1 DE 39 21 784 A1 US3,734,086 DE 92 00 249 U1 and KURUTSU, "The medical measurement technique in a diagnosis and biological signal analysis" (Medizinsche Mebetatechnik und Biosignalverarbeitung in der kardiologischen Diagnostic) of cardiopathy of Roland, M. -G.-Schmitz-Verlag Giebetaen 1984 122 - 129 pages, ISBN 3-922 272-23-1 is referred to.

The purpose of this invention offers the equipment and the approach for quantitive analysis of a somnipathy of detecting the failure encountered during sleep most correctly and completely, and enables it to also detect the failure of other physical actions produced from a somnipathy in addition to analysis of these failures. Especially this equipment and an approach mean detection of a heart beat failure (heart beat failure by the so-called apnoea). These purposes are attained by the property shown in the claim.

This invention is based on the following fundamental ideas in order to attain these purposes. In order to analyze a somnipathy and the failure accompanying this correctly for a short time, which body signal should be recorded or the need or ** becomes [how many parameters] very important so that the correlation of a body signal or contrast may express the cause of the failure. According to this invention from this reason, actuation of the oxygen density in heart potential and blood, a posture, and the body, the respiratory sound, positive pressure breathing, respiration rate, respiratory activities, and measurement of electronic physiological measured value can be performed by different sensor, and, thereby, offer of the synthetic data for analysis is possible. A working recorder is provided with the measured signal by the sensor, and it is memorized temporarily here, is read by computers, such as a personal computer, after completing a measurement cycle, and is processed. For this reason, the recorder is equipped with the storage card as external storage. This storage card is not only used for storage of a signal, but is programmed to be able to perform subsequent application before measurement. Selection of the specific sensor which suited the purpose by choosing a specific program by this approach is possible. Thus, by kicking an exception to two hardware, static or dynamic use like this equipment throat is also enabled. It can use also as a foundation of evaluation by being able to choose a desired time zone on the other hand, being able to display these data directly on PC monitor in the state of no correcting, and detecting the parameter of further others based on that data on the other hand for analysis of this measurement data. For example, a heart potential signal is supplied to a heartbeat analysis machine, and this judges change of a heartbeat from direct, other measured value, or a correlation with a histogram. Moreover, measured value is edited by suitable computer processing, for example, the display of it is attained in the form of a table or a histogram. Especially, the oxygen density of blood, posture change of a patient, a stertor activity, and respiratory insufficiency can be vividly displayed clearly by this approach. A positive pressure respiratory person's ***** is recorded in a therapy control unit. A somnipathy, respiratory insufficiency, a heart beat failure, etc. are detected through the correlation of these data, or a comparison. It is an advantageous point that the heart beat failure which considers a somnipathy as a cause is especially detectable. This kind of heart beat failure cannot perform sufficient treatment by the usual approaches, such as an arrhythmia inhibitor and an artificial cardiac pacemaker. However, if the causal relation of a heart beat failure and a somnipathy is detectable, a heart beat failure is removable from a cause by dealing with a somnipathy.

In analysis, the fall of the electrical potential difference of an environmental disturbance signal and distribution must be taken into consideration raising analytic effectiveness. Since the data stored by that time are applicable to evaluation even if there is sag under supervising a distribution electrical potential difference, the loss of data is avoidable. The disturbance signal which enters from a sensor cable is imposed on a filter with various kinds of frequency ranges, and in order to distinguish these signals by the factor from the disturbance field from a useful signal, the comparison with a useful signal is carried out. Thereby, room to be lost while these disturbance factors analyze is lost. Furthermore, since an alarm generating machine can also be formed, if the limit value to which the oxygen density and heartbeat of blood were set beforehand is reached, an alarm will operate and, thereby, the equipment use to a high-risk patient will be attained.

It is convenient to form a real-time clock in a recorder and to enable display on the real time of a signal and use of a time zone [****]. Therefore, a recorder is changed to the sleep mode and measurement is not started to desired time amount. This is convenient, especially when a recorder is set beforehand at a lab and sent to a patient after that.

As a special example, this invention can also record other electroencephalogram (EEG) signals and blood-pressure values of working equipment. Thereby, detection of the depth of an EEG signal to sleep is also possible.

The further significant point of the equipment based on this invention is by the comparison with a heart potential signal and the measured-value signal of the oxygen density of blood to be able to perform detection of a heartbeat or its change. In order to detect these change, it becomes unnecessary to measure blood pressure anew, since this is in change and the correlation of blood pressure.

The equipment by this invention is having the programmed recorder which records and memorizes the signal which the measurement sensor's caught, and offers a means to perform quantitive analysis

of a somnipathy. It follows, or (at the time of use by flight readiness) is transmitted to a computer at coincidence (at the time of use by the quiescent state), and these data are processed there. Graphical representation of the data measured and processed is carried out.

Below, based on a drawing, this invention is explained more at a detail.

<u>Drawing 1</u> a and b shows the example of selection of the detected numeric value in two different time intervals on time-axis criteria.

6 displays the analysis result containing patient data (<u>drawing 2</u> a) from <u>drawing 2</u> with a table (<u>drawing 2</u> b, 3b, 3d, 4a, 4c) and a graphic form (<u>drawing 3</u> a, 3c, 4b, 5, 6).

<u>Drawing 7</u> shows the schematic diagram of the equipment concerning this invention.

Drawing 8 shows evaluation of the 1st heartbeat signal.

Drawing 9 shows evaluation of the 2nd heartbeat signal.

Drawing 10 shows evaluation of a respiratory signal.

<u>Drawing 11</u> shows analysis of the 1st signal of the blood oxygen density from a pulse type oxygen analyzer. <u>Drawing 12</u> shows analysis of the 2nd signal of the blood oxygen density from a pulse type oxygen analyzer.

It explains to a detail more about the sensor used for below, and the measurement signal obtained by that cause first. The schematic-diagram side of the equipment concerning this invention is displayed on $\underline{\text{drawing } 7}$.

A patient's respiratory sound and stertor sound are recorded with the electric microphone 4 attached in the pharynx. The frequency range of this microphone is for 50 to 1500Hz. That envelope is scanned and digitized by the frequency which can be beforehand chosen with a configuration menu, after the analog signal curve obtained with this microphone is rectified and being applied to a filter. By the thermistor 5 or the thermal element, respiration rate (respiration rate of <u>drawing 1</u>) is obtained from a nose or opening by coincidence. Therefore, a set signal is formed and, on the other hand, this enables detection of the amplitude of breathing of the judgment of a respiration rate in another side. Thereby, the apnoea which will happen from now on is clearly discriminable from the sensor of the thorax described later and an abdomen conjointly. Respiratory actuation of a thorax is recorded by the piezo ceramic sensor 6 dedicated to the distribution box 15 for which various measuring cables gather. The pre amplifier for a measurement sensor is formed in this distribution box. The piezo ceramic sensor 7 is too used for measurement of abdomen respiratory actuation. In order to recognize actuation of hand and foot, at least one audit-trail sensor 8 is formed. This sensor is attached in a hand or a guide peg, and when the 2nd sensor connected to the 1st sensor through the Y character mold filter is used, actuation of either plurality becomes coincidence detectable among both hands and both guide pegs. Periodic actuation of hand and foot is detected by the means of these audit-trails sensor, and the comparison with heartbeat fluctuation is provided with this. An electrocardiograph (ECG) is used for heart potential measurement. For this reason, three electrodes 9 are attached in the usual measuring point of the body. The heart potential value of an analog is digitized and it memorizes as an ECG signal. The ECG signal of an analog is supplied to coincidence at a peak value detector for the measurement of a heartbeat based on the time amount interval between R peaks, and storage. The sensor is attached in a patient's finger although the oxygen density of blood is measured by the pulse type oxygen analyzer 10. Direct positive pressure breathing is moreover, detectable on a mask the inside of the measuring time like [at the time of the hyperbaric oxygen therapy of a nose with a pressure sensor 11. A pressure sensor is built into a separate heading together with a pre amplifier electronic circuitry and individual current supply. Measuring range is a -10 to 30mb range.

A posture is detected by the position sensor which becomes the last from four mercury switches. this position sensor -- facing the right, facing the left, and supine -- it looks down, and it stands, and it is stabilized and five postures of a location are shown. This position sensor can also be united with a distribution box. This position sensor can carry out the judgment with the real time for every sleep posture, and sleep difficult time amount, and can detect a different apnoea condition according to the situation of a posture by this, and offer of processing data is also possible for it. Both this position sensor and the piezo sensor for thorax respiratory actuation are the points which can unify to a distribution box and can reduce the measurement parts of the patient body by this, and it is especially advantageous.

The approximate account of the measurements process is carried out to below.

In advance of actual quiescence or migration inspection, equipment is programmed according to each use according to the flow chart of the storage card with which the recorder 3 was equipped. All physiological signals are memorized by this storage card during measurement. By reading a flow chart into an internal microprocessor from a storage card, a recorder is programmed and this is performed immediately after storage card insertion. The clock which shows real time to a recorder is formed and it can program to start in the time of day set beforehand or time. If after a program goes into power saving "a sleep mode", and becomes the set-up initiation time, and a switch will be turned on by the real-time clock and it will become halt assignment time amount, a switch will be turned off again. According to a configuration required for a medical problem and this medical (the number of channels, scanning frequency, start time, a stop time, patient data, etc.), a flow chart is written in a storage card by computer 1. According to the use demand of a storage card (PCMCIA-ATA standard), the thing of the anamnesis from 1.8 M bytes to 170 M bytes is usable. According to the memory capacity from which a storage card differs, creation of the physiology signal by different chart lasting time from different scanning frequency through a flow chart is attained from this. After reading into a computer, the physiological data memorized by the storage card are memorized, without producing an error like defect data, can newly [always] be analyzed, and can also be displayed. In the real-time actuation by the quiescent state, a recorder is connected to a direct computer through the serial interface used in order to transmit data to a period computer at the time of record.

In order to reduce a diagnosis [made / in according to the failure at the time of actuation in migration, or a patient's operation mistake / the mistake], a medical practitioner can investigate the right circumstances of record later. Therefore, for example, supply voltage is recorded, and when it becomes below the value to which this was set beforehand, record is stopped. The data recorded in between [till then] are applicable to analysis.

The functional condition of the recorder and a sensor after being applied is manageable on the real-time display on a computer. Application management will be performed by the light emitting diode (LED) lamp formed in the front face of a recorder if acquisition of a computer cannot be performed. The static test mode for 5 minutes is started after reading of a flow chart, and a light emitting diode lamp illuminates the adaptation part of the sensor assigned, respectively. A push on the marker key 13 reboots a test program. The marker key is prepared so that a patient can record a special occurrence like [when a patient occurs in the dead of night].

Although drawing 6 shows the example of evaluation of a measurement cycle from drawing 2, data are expressed as a different approach here. The signal specified by the rough version is displayed about the desired time zone as a function of time amount. The measurement data of the oxygen content of blood, an attitude sensor, an electric microphone, and the piezo-electric sensor for respiratory actuation detection are estimated by the statistical method, and are displayed in the table and the histogram format. Heartbeat distribution (<u>drawing 4</u>) is shown by the graph. In addition to it, the time dependency of data can display like drawing 1. Especially about time amount progress of a measurement signal, it can display in the combination of any requests and whenever [effect / of the specific heart beat failure over a somnipathy can be evaluated from the combination display of the parameter of breathing and the heart. These heart beat failure is most often observed in time amount trace of a heartbeat, and is detected quantitatively and qualitatively in the case of evaluation. Heartbeat fluctuation is detected automatically and, thereby, a heartbeat characteristic is calculated. A heartbeat signal is compared with the signal of an audit-trail sensor in order to distinguish the fluctuation of a periodic heartbeat produced by sleep apnea from the fluctuation which results from an involuntary convulsion. Respiratory related matters, such as respiratory insufficiency concerning sleep, are also analyzed quantitatively and qualitatively during evaluation, and are displayed with the index with which the count results based on this differ. These are also shown by the tabular format as shown in the drawing 2 lower part. Distinction of the apnoea in which the hypopnea, an obstructive apnoea and the apnoea of a central nervous system, and they were intermingled by application of the special analysis algorithm described later is possible for this invention. Furthermore, in the automatic analysis of an apnoea and the hypopnea, the pressure variation recorded by the hyperbaric oxygen therapy of a nose is used instead of a respiration rate signal, and enables therapy management with

this exact.

With the synthetic data ingredient whose offer to a medical practitioner is attained by this invention, a medical practitioner becomes possible [that an exact diagnosis can be drawn about a somnipathy, respiratory insufficiency, and a heart beat failure]. The treatment which suited the purpose is attained at the patient who takes charge.

The following interrelations automatically performed within the limits of this invention as an example are possible.

- 1. A stertor sound and the interrelation of an oxygen fall show an obstructive apnoea.
- 2. The interrelation of the rhythmical actuation (PLMs, involuntary convulsion) and the rhythmical heartbeat of a guide peg without a stertor sound and an oxygen density fall shows whenever [accompanied by the evocation effectiveness to the cardio-vascular system by actuation of a guide peg / effect].
- 3. The arrhythmia without other signals and interrelations shows actual arrhythmia.
- 4. The arrhythmia which synchronized with the respiratory signal shows the arrhythmia involved in the arrhythmia and the apnoea of sinus.
- 5. The compensation arrhythmia without other signals and interrelations shows overventricle contraction.
- 6. The regular oxygen density fall which synchronized with interruption of a blood flow and actuation of a thorax and an abdomen shows a central nervous system apnoea.
- 7. The oxygen density fall covering the long duration which happens with the fall of an agnogenic respiratory parameter, slow change of a heartbeat, etc. shows an obstructive lung disease.
- 8. The strong apnoea which synchronized with the oxygen density fall strongly, and synchronized also with heartbeat change although it was still smaller shows the dysautonomica (it is (like the case of too much diabetes mellitus)).
- 9. It is shown that the fall of the heartbeat after change into the posture which became width from the posture which stood went into sleep. Even when actuation of an apnoea or a guide peg takes place to coincidence, the time amount by which the patient went into sleep can be detected in a slight error range.
- 10. When a change irregular to all signals takes place to coincidence and this continues from about 20 minutes for about 1 hour and every half for 40 minutes, RME sleep (dream sleep) is shown.
- 11. The usual stertor accompanied by the periodic increment in an alignment stay without an oxygen density fall shows sky path resistance syndrome (Upper Airways Resistance Syndrome).
- 12. The absolute value of the difference of thorax actuation and abdomen actuation is detected as an accident rate, and is displayed on a graph. (Being for example, an additional channel) Below, the evaluation algorithm about heartbeat analysis, the detection algorithm of an apnoea and

the hypopnea, and the algorithm of oxygen density fall detection are described.

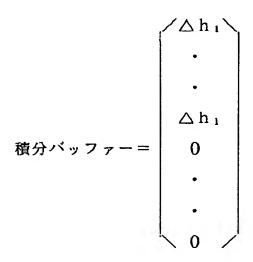
Physiological data are visually estimated by one side based on rough data, and, on the other hand, are estimated by the automatic evaluation program of a computer.

The algorithm for detection of stay [a heartbeat automatic analysis alignment] fluctuation (sinus arrhythmia involved in an apnoea)

In this case, R peak distance and the so-called tachogram are used.

This algorithm separates from a table with the increment in a heart rate as follows. Each heartbeat is displayed by hi and **hi shows the difference from hi.

The maximum persistence time of the increment in algorithm n= of the increment detection in a heartbeat - i= 1,, n It receives and **hi=hi-hi-1 **hi is incorporated to an integral buffer. An integral buffer is a n vector and is initialized by zero.



- The sum total is computed from each vector element.

積分 =
$$\Sigma$$
 Δh_k

- a case -- exception ** Integral < -- 0 The time: The cardiogram descends. An integral buffer is initialized by zero.

integral [buffer i] =0; i= 1, ..., n 0 < -- Integral < -- Threshold value The time: Although the cardiogram goes up, it is not enough.

Integral > Threshold value At the time: The cardiogram goes up even to threshold value at least. The 1st decision criterion of an event is met.

- Retrieval of maximum Maximum is verified from the point that a rise starts. This is obtained by comparing a heartbeat value.

n= 1, ..., end of a table Readings > Present condition maximum At the time: Value = Maximum A new value is read.

readings < -- Present condition maximum The time: | value maximum | <= Discontinuity threshold value: Although the cardiogram descends again, it is not a thing to the extent that it is concluded that the rise finished. Verification of maximum is continued.

| Value maximum | > Discontinuity threshold value: The cardiogram decreases to discontinuity threshold value at least. Thereby, maximum is detected. The start point of heartbeat change and an ending point are searched starting with the detected maximum.

- Retrieval of the start point of a rise It returns in time, it starts with this detected maximum, and the start point of a rise, i.e., the 1st minimum value, is searched. This retrieval is performed like the time of maximum. The numeric value of a table is searched to the end of a pre- rise to hard flow, however max can have even "the ending point of the retrieval interval of the 1st minimum value", and can be made into a limit, and this value can be beforehand chosen by the user.

the front minimum value, ..., maximum Receive. : Readings < -- The 1st minimum value of the present condition The time: Value = The 1st minimum value A new value is read.

Readings > The 1st minimum value of the present condition At the time: | value-1st minimum value | <= Discontinuity threshold value: Although the cardiogram goes up again, it is not the degree regarded as having resulted in the start point of a rise. Retrieval of a start point is continued. | Value-1st minimum value | > Discontinuity threshold value: The cardiogram goes up again to the value of discontinuity threshold value at least. Thereby, the start point of a rise is detected. Now, the

ending point of a rise is decided at the following steps.

- Retrieval of the ending point of the increment in a heartbeat It returns in time, it starts with the detected maximum, and the ending point of a rise, i.e., the 2nd minimum value, is searched. This retrieval is performed like the time of the 1st minimum value. The numeric value of a table is advanced until the minimum value is detected by hard flow, however max can have even "the ending

point of the retrieval interval of the 2nd minimum value", and can be made into a limit, and this value can be beforehand chosen by the user.

i= 1, ..., n Receive. : Readings < -- The 2nd minimum value of the present condition The time: Value = The 2nd minimum value A new value is read.

Readings > The 2nd minimum value of the present condition At the time: | value-2nd minimum value | <= Discontinuity threshold value: Although the cardiogram goes up again, it is not the degree regarded as having resulted in the ending point of a rise. Retrieval of an ending point is continued. | Value-2nd minimum value | > Discontinuity threshold value: The cardiogram decreases again to the value of discontinuity threshold value at least. Thereby, the 2nd minimum value is detected. Each parameter plays an important role in this case like SaO2 analysis. Since a heartbeat signal is more complicated than SaO2 signal, a characteristic phenomenon happens more violently. The typical example of heartbeat analysis is shown in drawing 8.

Analysis parameter of heartbeat analysis Here, each selectable parameter is explained in full detail once again beforehand.

- Increment in the minimum heartbeat epsilon [1, 30]
- The cardiogram decides it that this value begins to search maximum which to have to go up. With an algorithm, this value is a limits-of-integration value.
- The maximum time amount interval to the increment in Hf epsilon [1,250] This value defines the limitation of the duration which reduction of Hf curve starts. With an algorithm, this determines an integral buffer size.
- Discontinuity threshold value of the minimum-maximum retrieval epsilon [1, 10] Discontinuity threshold value serves as a discontinuity decision criterion for searching the minimum value or maximum, when Hf curve changes to this value.
- Event time amount of the minimum value and maximum epsilon [1,250]
- In the long run, let these two parameters be the decision criteria of whether to take up in an event list by making the detected increment in a heartbeat into an event. In order to take up as an event, the time course of an increment must agree below.

Minimum event time amount <(t2 nd min=t1st min) < maximum event time amount - Retrieval interval of maximum epsilon [1, 30]

The limitation of the retrieval environment for retrieval of maximum is defined, and it starts from a present condition value, therefore the value turns into provisional maximum.

- Retrieval interval of the 1st minimum value epsilon [1, 30]
- This retrieval interval defines the limitation of the retrieval environment for searching the start point of the increment in a heartbeat. In addition to discontinuity threshold value, this interval becomes the 2nd discontinuity decision criterion. This will achieve the duty are continued by performing an algorithm and which carries out thing prevention, if a heartbeat reaches a stable value (<u>drawing 8</u>).
- Retrieval interval of the 2nd minimum value epsilon [1, 30]
- This retrieval interval defines the limitation of the retrieval environment for searching the last point of an increment. In addition to discontinuity threshold value, this interval becomes the 2nd discontinuity decision criterion. This will achieve the duty are continued by performing an algorithm and which carries out thing prevention, if the cardiogram reaches a stable value (drawing 9). Selection of a fundamental parameter is -. The increment in the minimum heartbeat 8- Discontinuity threshold value of the minimum-maximum retrieval 8- The retrieval interval of maximum 30s- The retrieval interval of the 1st minimum value 10s- The retrieval interval of the 2nd minimum value 10s- The minimum event time amount Algorithm of 150s respiratory channel apnoea and hypopnea retrieval An algorithm is carried out by the three-stage.
- Filtering [of current data] Calculation [of limiting value] Implementation of the analysis based on edited data The signal of a respiratory channel is complicated, and since disturbance tends to enter, it is necessary to hang on a filter. That filtering is floating or in smooth, although it carries out at the rate for 1 second each, this is equivalent to the scanning value of 250 pieces.

Filtering of data The instantiation value of each respiratory channel is expressed with fi.

i= -- 1, ..., 250 ******* -- **fi=fi-fi-1 **fi is taken up to a differential buffer. A differential buffer is initialized by zero by the 250-dimensional vector.

 $s u m_k = \sum \triangle f_i$

Calculation of the total value of an integral buffer

k=1

These values are used for the following count.

An apnoea or the hypopnea has the description in the spirogram carrying out the rate descent of fixed as compared with pre- breathing. Breathing always draws a sign curve, and since the amplitude is changed even if it is a healthy person, in order to detect reduction in a breath, it needs to compute the average using pre- breathing. This is performed by the following algorithm.

It is an algorithm for retrieval an apnoea / whenever [respiratory low minimum]. The average is computed by the minimum value and maximum of ten breathing just before.

Retrieval of maximum sumi> 0: sumi+1> maximum > When 0, i.e., the spirogram, is still going up Maximum = sumi+1 When sumi+1<0, i.e., the curve, is already over maximum The maximum by which last time was computed is effective as it is.,

Retrieval of the minimum value sum<0: When sumi+1< minimum value <0, i.e., the spirogram, is still descending Minimum value =sumi+1 sumi+1> When 0, i.e., a curve, is already over the minimum value The minimum value by which last time was computed is effective as it is., The average is computed based on the value of the computed minimum value and maximum.

An apnoea / whenever [respiratory low minimum] are computed by the following from this. イベント限界値 * 平均

Event threshold value is chosen here at a percentage.

It means that the auxiliary numeric value required for all analysis at this had gathered. algorithm for an apnoea and hypopnea retrieval i=-1, ..., 250 receiving -- if -- |sumi| -- < -- Threshold value The time counter =0 -- setting -- count initiation if -- |sumi|> Threshold value The time Which confirms whether the counter went up.

The minimum event time amount < counter < maximum event time amount At the time An apnoea or the hypopnea is detected.

This analysis is carried out about all respiratory channels. An obstructive apnoea and a central nervous system apnoea are distinguished based on the activity of a thorax and an abdomen. When respiratory activities decrease through opening and a nose, a program confirms whether the activity of a thorax and an abdomen also decreased from correlation with the program itself. If it is decreasing, there is misgiving of a central nervous system apnoea. <u>Drawing 10</u> shows the analysis for apnoea retrieval.

Analysis parameter of apnoea analysis The parameter of apnoea analysis is determined by medical diagnosis. The following parameters are selectable.

- Apnoea threshold value In order to diagnose as an apnoea, the spirogram must descend at least 80% compared with the average of ten last breathing. With an algorithm, this value is equivalent to event threshold value.
- The minimum apnoea time amount This value expresses the limitation of a time amount interval that the spirogram results in apnoea threshold value.

The minimum apnoea time amount needs to continue for at least 10 seconds.

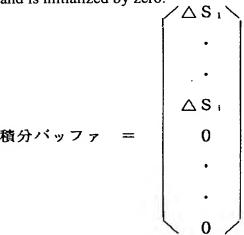
- Respiratory low minimum community value In order to diagnose as the hypopnea, the spirogram must descend at least 50% compared with the average of ten last breathing. With an algorithm, this value is equivalent to event threshold value.
- The minimum hypopnea time amount This value expresses the limitation of a time amount interval that the spirogram is below a respiratory low minimum community value. The minimum hypopnea time amount needs to continue for at least 10 seconds.
- Central nervous system apnoea threshold value In the case of a central nervous system apnoea, the amplitude of the signal of a thorax and an abdomen must descend at least 80% compared with the average of ten last breathing.
- The minimum central nervous system apnoea time amount This value expresses the limitation of a time amount interval that the curve of a thorax and an abdomen results in central nervous system apnoea threshold value. The minimum apnoea time amount needs to continue for at least 5 seconds.
- Maximum hour duration This value shows the limitation of the maximum hour duration of serious amplitude reduction in one event.

Algorithm for oxygen density channel oxygen density fall detection The purpose of this algorithm is retrieval of an oxygen density fall. Since there are very many measurement sizes of an oxygen density, they need reduction of data to accumulate in quick analysis. The table showing the average for 1 second is prepared for this data reduction. Even if it carries out like this, since the oxygen densities of the blood for 1 second are few as compared with a heartbeat, they are not having lost information. Then, this algorithm searches this table for an important event.

Here, Si shows each value of SaO2 in a table, and **Si expresses a difference with Si.

The maximum elapsed time of retrieval algorithm n= descent of an oxygen density fall - i= 1, ..., n It

receives and **Si=Si-Si-1 **Si is incorporated to an integral buffer. An integral buffer is a n vector and is initialized by zero.



- Total value is computed from each vector element.

積分 =
$$\Sigma$$
 \triangle S k k=0

- a case -- exception ** Integral > 0 The time: SaO2 curve goes up, namely, a concentration fall is not seen. An integral buffer is initialized by zero.

Integral [buffer i] =0; i= 1, ..., n Threshold value > Integral > 0 At the time: SaO2 curve is not so large as anxious about a concentration fall, although it descends.

integral < -- Threshold value The time: SaO2 curve decreases to threshold value at least. The 1st decision criterion of a concentration fall is met.

- Detection of the minimum value Retrieval of the minimum value is performed starting with descent. This is obtained by comparing with the SaO binary.

end of n=1, ..., a table Reading value < -- Present condition minimum value: The value = minimum value A new value is read.

Reading value > Present condition minimum value: | value minimum |<= discontinuity threshold value: Although SaO2 curve goes up again, it is not so large as it is concluded that the concentration fall was completed. Retrieval of the minimum value is continued.

| Value minimum |> discontinuity threshold value: SaO2 curve goes up again even to discontinuity threshold value at least. Thereby, the minimum value is detected. It begins from this detected minimum value, and the start point and the ending point of a concentration fall are searched.

- Retrieval of the start point of a concentration fall It returns, time amount is begun from the start point of the detected minimum value, i.e., a concentration fall, and the 1st maximum is searched. This retrieval is performed by the same approach as retrieval of the minimum value. Although searched in the range in which it is advanced until the value of a table continues till the last of a preconcentration fall to hard flow, however many do not exceed "the ending point of the retrieval interval for the 1st maximum", this value is selectable beforehand by the user.

Just before maximum, ..., minimum value: Reading value > The 1st maximum of the present condition At the time: Value = the 1st maximum A new value is read.

reading value < -- The 1st maximum of the present condition The time: | value-1st maximum |<= discontinuity threshold value: Although SaO2 curve descends again, it is not so large as it is concluded that the start point of a concentration fall was reached. Retrieval of a start point is continued.

| Value-1st maximum |> discontinuity threshold value: SaO2 curve descends again to discontinuity threshold value at least. Now, since it resulted in the pre- concentration fall, the 1st maximum is detected. The ending point of a concentration fall is searched with the following step.

- Retrieval of the ending point of a concentration fall It advances to a front on a time-axis, it begins

from the detected minimum value, and the ending point of a concentration fall, i.e., the 2nd maximum, is searched. This retrieval is performed like retrieval of the 1st maximum. Although the value of a table is advanced in front until maximum is detected, many do not exceed "the ending point of the retrieval interval of the 2nd maximum", and this value can be beforehand chosen by the user.

i= 1, ..., n It receives. : Reading value > The 2nd maximum of the present condition At the time: Value = the 2nd maximum A new value is read.

reading value < -- The 2nd maximum of the present condition: | value-2nd maximum |<= discontinuity threshold value: Although SaO2 curve descends again, it is not so large as it is concluded that the ending point of a concentration fall was reached. Retrieval of an ending point is continued.

| Value-2nd maximum |> discontinuity threshold value: SaO2 curve descends again to discontinuity threshold value at least. Thereby, since it resulted in the next concentration fall, the 2nd maximum is detected

This is explanation of a fundamental algorithm. Appropriate selection of an analysis parameter plays a role important for effective functional exertion of an algorithm. SaO2 analysis is shown in <u>drawing</u> 11.

Analysis parameter of SaO2 analysis As stated previously, the effectiveness of an algorithm is applied to selection of a suitable parameter. All parameters can be chosen freely. Below, these are explained again more at a detail.

- Minimum SaO2 descent epsilon [-10, -1]

In order to begin retrieval of the minimum value, an oxygen density curve must descend what%, or this value is boiled, and is decided more. In an algorithm, this value is a limits-of-integration value.

- The minimum time amount interval of SaO2 descent epsilon [1,250]

This value defines the limitation of a time amount interval that descent of SaO2 curve must take place. An algorithm shows an integral buffer size.

- Discontinuity threshold value for the maximum-minimum retrieval epsilon [1, 10] Discontinuity threshold value is the discontinuity decision criterion of the minimum value when SaO2 curve changes to this value, or maximum.
- Event duration of the minimum value and maximum epsilon [1,250]

In the long run, these two parameters serve as a decision ingredient of whether to take up on an event list by making the detected concentration fall into an event. In order to take up as an event, the duration of an increment must suit below.

the minimum event time amount < (t2 nd max-t1st max) -- < -- Maximum event time amount - Retrieval interval of the minimum value epsilon [1, 30]

The limitation of the retrieval environment for the minimum value retrieval which begins from the present condition is defined, and this serves as [therefore] the provisional minimum value.

- Retrieval interval of the 1st maximum epsilon [1, 30]

This retrieval interval defines the limitation of the retrieval environment for start point retrieval of an oxygen density fall. In addition to discontinuity threshold value, this interval is the 2nd discontinuity decision criterion. This prevents that an algorithm continues being performed, when an oxygen density results in a stable value.

- Retrieval interval of the 2nd maximum epsilon [1, 30]

This detection interval defines the limitation of the retrieval environment for the termination check funiculus of an oxygen density fall. In addition to discontinuity threshold value, this interval is the 2nd discontinuity decision criterion. This prevents that an algorithm continues being performed, when an oxygen density results in a stable value (<u>drawing 12</u>).

Selection of a fundamental parameter is:-. Minimum SaO2 descent: - 4%- Discontinuity threshold value for the minimum-maximum detection 2%- The retrieval interval of the minimum value 30s- The retrieval interval of the 1st maximum 30s- Retrieval interval of the 2nd maximum 30s- Minimum event time amount: 5s- The maximum event time amount 150s

[Translation done.]